Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

M-2, Part VI
Chapter 2

February 16, 1994

1. Transmitted is a complete revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," Chapter 2, "Quality Improvement."

2. Principal changes are:

a. Paragraph 2.02: Establishes policy for Quality Improvement Programs.

b. Paragraph 2.03: Provides policy for inspection and accreditation of all sites that perform patient care tests.

c. Paragraphs 2.04 through 2.09: Establish the required elements for quality improvement in the main clinical laboratory and ancillary testing sites.

3. Filing Instructions:

Remove pages	Insert pages
2-i through 2-2ii	2-i through 2-ii
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	2C-1 through 2C-5
	2D-1 through 2D-7

4. RESCISSIONS: M-2, Part VI, Chapter 2, dated July 10, 1989, changes 71 and 72; and VHA Circulars/Directives: 10-80-003, 10-81-013, 10-81-285, 10-82-214, 10-83-046, 10-84-019, 10-84-114, 10-84-194, 10-85-169, 10-86-121, 10-89-121, 10-89-097, 10-92-089.

Signed 2/16/94 by Dennis Smith for

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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part VI, Chapter 2, dated July 10, 1989,; and changes 71 and 72

2. Circulars/Directives

10-80-003
10-81-013
10-81-285
10-82-214
10-83-046
10-84-019
10-84-114
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CHAPTER 2. QUALITY IMPROVEMENT

2.01 PURPOSE

This chapter establishes policy for the structure of quality improvement programs for laboratory testing in all Department of Veterans Affairs (VA) medical centers, their outreach functions and ancillary testing sites. This chapter applies to all sections of the main clinical laboratory, their associated outpatient clinic laboratories, and ancillary testing sites that perform patient care tests.

2.02 POLICY

a. The VA medical center must provide an ongoing, comprehensive continuous Quality Improvement Program under the direction of the Chief, Pathology and Laboratory Medicine Service, which:

(1) Evaluates the effectiveness of the laboratory's and the medical center's policies and procedures in providing the highest quality Laboratory medicine test results and anatomic pathology reports;

(2) Improves the overall quality of care provided to each patient, as well as identifying and correcting problems;

(3) Ensures the availability of accurate, reliable, and timely laboratory medicine test results, and anatomic pathology reports to the patient's physician;

(4) Documents all quality improvement activities; and

(5) Utilizes existing VA policy established in MP-5, Part I, Chapter 430, "Performance Management System," to ensure quality performance of the staff.

b. The VA medical center will ensure conformance of its policies and procedures for all sections of the laboratory and ancillary testing sites with the current standards and accreditation requirements of College of American Pathologists (CAP), Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), and American Association of Blood Banks (AABB) (see Ch. 13).

c. The VA medical center will ensure satisfactory performance on required interlaboratory proficiency testing as detailed in paragraph 2.06.

d. The VA medical center will ensure compliance with standardization of analytes (see Ch. 4), i.e., that all testing of a specific analyte performed within the facility is performed by methodologies proven to be comparable, and which have the same reference ranges, in order to prevent misinterpretation of test results.

2.03 INSPECTION AND ACCREDITATION

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a. The CAP Commission Laboratory on Accreditation is the primary inspection and accreditation agency for all laboratory testing sites in VA medical centers. The Director of each VA facility will ensure current registration of all testing sites that perform laboratory tests for patient care with CAP. NOTE: The costs of accreditation and biannual inspection will be borne by the nationwide contract initiated by the Director, Pathology and Laboratory Medicine Service, VA Central Office.

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b. The Director of each VA facility will ensure current compliance with JCAHO standards for quality assurance. NOTE: The costs of accreditation and inspection will be borne by the facility.

c. The Director of each VA facility that has a Blood Bank and/or performs transfusion medicine services will ensure current inspection and accreditation of the facility with AABB. NOTE: The costs of membership, or alternatively of accreditation and biannual inspection, will be borne by the facility.

d. The Director of each VA facility is mandated to participate in the annual registration and inspection process of the Food and Drug Administration (FDA) if the medical center draws blood or prepares components, even though the FDA has no regulatory control over the VA facility.

e. On a periodic basis, CAP, JCAHO, AABB, and FDA will summarize and submit the findings of their inspection and accreditation processes to Pathology and Laboratory Medicine Service, VA Central Office, and to the individual facilities.

f. Responsibilities

(1) The Director, Pathology and Laboratory Medicine Service, VA Central Office, will provide oversight responsibility for ensuring current accreditation with each of the aforementioned groups/agencies. In those instances where problems having a potential for adverse patient outcome are identified and require corrective action, VA Central Office will work with the Chief, Pathology and Laboratory Medicine Service, at the facility to ensure that corrective action is implemented in a timely manner.

(2) The Director of each VA facility will provide the necessary oversight and resources to ensure that the required accreditation programs are fully implemented.

2.04 REQUIRED ELEMENTS FOR QUALITY IMPROVEMENT IN MAJOR DIVISIONS OF THE LABORATORY AND ANCILLARY TESTING SITES

a. General Program Requirements For All Laboratory Sections. The Chief, Pathology and Laboratory Medicine Service, is directly responsible for:

(a) The accurate and prompt reporting of laboratory test results, and ensures that if tests are performed in a reference laboratory, the name of the laboratory performing the test is included in the report placed in the patient's record (see Ch. 11).

(b) Ensuring that appropriate written policies and procedures are in place for a comprehensive Quality Improvement Program designed to monitor and evaluate the overall quality of the laboratory testing process in all testing sites in the medical center and its outreach functions.

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(c) Testing performed within the Pathology and Laboratory Medicine Service.

(d) Serving as the quality improvement compliance officer for testing performed outside the Pathology and Laboratory Medicine Service, such as point of care testing, and blood gases, (see Ch. 10).

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(e) Assisting the hospital quality management staff in routinely reporting quality management information as part of the Quality Improvement Checklist (QUIC) under the auspices of the Office of Quality Management, VA Central Office (see App. 14D).

(2) Medical Administration Service (MAS) is responsible for proper identification of each patient, and proper input and maintenance of patient information in the MAS software package for the Decentralized Hospital Computer Program (DHCP).

(3) Pathology and Laboratory Medicine Service must have:

(a) An ongoing mechanism for monitoring and evaluating the corrective action of the Quality Control elements required in paragraph 2.05, including:

1. Problems identified during the evaluation of calibration and control data for each test method.

2. Problems identified during the evaluation of patient test values for the purpose of verifying the reportable reference range for the test method.

(b) An ongoing mechanism for monitoring and evaluating the effectiveness of the corrective action taken for the main clinical laboratory as a whole, and all ancillary testing sites for any unacceptable, unsatisfactory or unsuccessful proficiency testing required under paragraph 2.06, and in Chapters 10 and 13.

(c) A mechanism to identify and evaluate patient test results which appear inconsistent with other patient information, including, but not limited to, age, sex, and diagnoses.

(d) An ongoing mechanism for monitoring and evaluating the competency of personnel involved in all aspects of laboratory testing as defined in MP-5, Part I, Chapter 430.

(e) An ongoing mechanism for documenting communications problems between laboratory personnel and the authorized individual who orders the tests and/or receives the test results. This system must include all shifts and must include corrective action taken to resolve the problems.

(f) A system in place to assure that all complaints and problems reported to the laboratory are documented. Investigation of complaints and patient incident reports must be made, and corrective action instituted when indicated.

(g) An ongoing mechanism for:

1. Documenting and assessing problems identified during quality assessment reviews;

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2. Discussing them with the staff; and

3. Taking and documenting corrective action to prevent recurrences.

(h) An ongoing mechanism for monitoring and evaluating the usefulness and appropriateness of referral testing, i.e., that testing is sent to a CLIA-accredited laboratory and that the results obtained are of high quality.

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(4) If testing is performed using different methodologies, instruments, or testing sites in the VA medical center, the Pathology and Laboratory Medicine Service must compare the relationship of test results at least twice yearly to ensure there is consistency in reporting:

(a) Reference intervals,

(b) Imprecision (coefficient of variation) and

(c) Other patient-related information to physicians.

b. Required Program for Blood Banks and Transfusion Services. The Blood Bank Transfusion Section, must have an ongoing mechanism for monitoring and evaluating those aspects of care that are most important to the health and safety of the patient, including the incidence of various types of transfusion reactions.

(1) All hemolytic and other life-threatening transfusion reactions must be immediately reported to the patient's physician.

(2) All hemolytic and other life-threatening transfusion reactions must be reported through the medical center's Patient Incident Reporting Program. NOTE: This data must then be forwarded to the Region and to Pathology and Laboratory Medicine Service, VA Central Office in accordance with M-2, Part I, Chapter 35.

(3) Patient Incident Reports, or Occurrence Screening Reports involving problems in pre-transfusion compatibility testing, must be monitored and analyzed on a regular basis.

(4) The incidence of errors in the labeling of donor units drawn by the facility must be monitored and analyzed on a regular basis.

(5) All errors in labeling of donor units drawn at the facility must be reported to FDA. This includes:

(a) ABO (used to represent the names of the major blood groups)/Rh;

(b) Incomplete disease marker testing;

(c) Inappropriate interpretation of disease marker testing; or

(d) Mislabeling of the unit.

(6) All errors in labeling of units received from other blood centers must be reported to the drawing facility.

NOTE: The Blood Bank section must also follow the quality improvement elements detailed in Chapter 5.

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c. Required Program for Anatomic Pathology

(1) Pathology and Laboratory Medicine Service must have an ongoing mechanism for monitoring and evaluating those aspects of care that are most important to the health and safety of the patient, including:

(a) The communication of surgical pathology and cytopathology diagnoses to attending physicians and medical personnel authorized to receive and/or transmit diagnoses.

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1. All new malignancies, except as noted in Chapter 6, must be communicated to the designated personnel responsible for taking appropriate action, as defined in Chapter 6.

2. In all cases where a modified report involving a clinically significant change in diagnoses, or therapy is made, the report must be communicated to designated personnel responsible for taking appropriate action (see Ch. 6).

(b) Any potential and actual detrimental patient outcomes resulting from delays in surgical pathology or cytopathology diagnoses (see Ch. 6, for details regarding the expected turn-around-times for specific types of anatomic pathology reports.)

(c) Any potential and actual detrimental patient outcomes resulting from incorrect surgical pathology or cytopathology diagnoses.

(2) Pathology and Laboratory Medicine Service must provide an autopsy service in accordance with Chapter 9, where:

(a) Autopsy reports are issued in a timely manner, and

(b) The findings of those reports are able to be used as a source of clinical information in quality assessment, and in the improvement activities of the clinical services.

d. Required programs for all Pathology and Laboratory Medicine Service sections (see Ch. 4).

(1) Pathology and Laboratory Medicine Service must have an ongoing mechanism for monitoring and evaluating those aspects of care that are most important to the health and safety of the patient, including:

(a) The communication of critical laboratory values, i.e., those results which are considered imminent, life-threatening laboratory results.

1. All critical laboratory values must be immediately communicated to designated personnel responsible for taking appropriate action.

2. Documentation of the communication regarding the critical laboratory value must include the person contacted, and date and time contacted. This documentation must become part of the patient's permanent record.

(b) Any errors detected in verified, reported results.

1. All changes in verified results must be properly documented in accordance with the standards of CAP.

2. Pathology and Laboratory Medicine Service should have a system which periodically monitors the incidence of pre-analytical, analytical, and

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postanalytical errors by cause and by clinical significance, for purposes of outcome measurement (see Ch. 14).

(c) The timely reporting of emergency test results.

(2) Pathology and Laboratory Medicine Service must have an ongoing local mechanism for monitoring, evaluating, and improving, if necessary, the elements required under paragraph 2.08, Patient Test Management, including:

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(a) The criteria established for:

1. Patient preparation,

2. Specimen collection,

3. Specimen labeling,

4. Specimen preservation,

5. Specimen storage, and

6. Specimen transportation.

(b) The completeness, relevance and necessity of information solicited and obtained on the laboratory test requisition, or computer order.

(c) The use and appropriateness of the criteria established for specimen rejection.

(d) The accuracy, completeness and usefulness of the test report information necessary for appropriate interpretation, or utilization of the results.

(e) The timely reporting of test results based on urgency.

(f) The accuracy and reliability of the test reporting systems.

(g) The appropriateness of test result storage and retrieval.

(h) The reportable range for test results.

2.05 QUALITY CONTROL

a. The Chief, Pathology and Laboratory Medicine Service, ensures that there is a written policy for quality control for each test method performed in each testing site in the facility. This includes clearly defined:

(1) Goals,

(2) Procedures,

(3) Tolerance limits, and

(4) Corrective action and related information.

b. All changes in quality control ranges must be documented and submitted to the Chief, Pathology and Laboratory Service, or appropriate designee.

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c. All test procedures must be monitored by acceptable internal and external Quality Control Programs to ensure accuracy and reliability of testing.

d. The quality control materials must be tested in the same manner as the patient specimens. Immediate action must be taken, along with proper documentation, whenever the Shewhart-Westgard quality control rules are violated.

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e. Weekly, and monthly reviews by the Chief, Pathology and Laboratory Medicine Service, or qualified designee, must show evidence of active review of Quality Control Programs with documentation of all corrective actions taken.

f. A monthly summary of the laboratory's quality control problems must be forwarded to the facility's Pathology and Laboratory Medicine Quality Improvement Committee for review.

g. The quality control records must be kept for a minimum of 2 years.

h. An internal Quality Control Program with written standards must be established at the facility for each test method.

(1) The Chief, Pathology and Laboratory Medicine Service, is responsible for establishing standards and policies concerning an internal Quality Control Program that is practical and effective in preserving quality testing in the laboratory. NCCLS (National Committee for Clinical Laboratory Standards) protocol, C24-A, on "Internal Quality Control Testing: Principles and Definitions," should be used as a recommended guideline (see subpar. 4.12g).

(2) All internal Quality Control Programs must have a written document for the design and evaluation of the program.

(a) There must be a written protocol in operation to routinely detect:

1. Clerical errors,

2. Significant analytical errors, and

3. Unusual laboratory results, which include critical values.

(b) A mechanism is necessary to provide for the timely correction of errors.

(c) As a minimum, a two-level control material must be used each day of testing For some critical tests more than two-level control material and more frequent testing may be required to ensure accuracy of testing, i.e., two-level control material, at a minimum, every 8 hours for blood gases.

(d) The quality control results must be actively reviewed, initialed and dated by the section supervisor, or designee, each day the test is employed. DHCP Levy-Jennings quality control charts and monthly summary reports must be initialed monthly by the Chief, Pathology and Laboratory Medicine Service, or designee,

(e) There must be complete and detailed documentation of corrective action taken when the control values exceed defined tolerance limits and violate the quality control action rules. A corrective action report must be written for

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any unacceptable quality control result, and must be submitted to the Chief, Pathology and Laboratory Medicine Service, or designee, prior to the service's monthly Quality Assurance Meeting.

(f) If the quality control problem becomes frequent, an in-service continuing education service must be provided.

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(g) Whenever possible, another type of internal quality control in the form of periodic blind retesting of patient specimens should be done.

1. Depending on the critical nature of the tests, on a periodic, randomly-selected specimens from the previous day's run should be submitted for reanalysis to ensure repeatability and reliability of the analytical testing process. The interval time period for random testing will be determined by the Pathology and Laboratory Medicine Quality Improvement Committee.

2. There must be defined acceptable limits, which must be reviewed and documented by the Chief, Pathology and Laboratory Medicine Service, or designee, in a timely manner.

(h) If there is any doubt about the integrity of the quality control, or calibration materials being used (i.e., instability or degradation), the laboratory section in question should recalibrate with another lot of calibrator then verify calibration with reference to instrument means of the commercial controls, or group means from reference material (CAP). NOTE: It is not cost effective to establish accuracy with both reference method and reference material.

(i) For qualitative tests, quality control will include positive as well negative quality control specimens with each batch of analyses.

(j) For electrophoresis, at least one control sample, containing fractions which are representative of those routinely evaluated in patient specimens, must be used in each electrophoretic plate.

(k) For quantitative radial immunodiffusion, immunoelectrophoresis, ELISA methods, at least two control samples must be run with each plate. For immunochemistry tests, particular attention should be given to the potency of antibodies when exceeding the expiration date. Particular attention should be given to any abrupt changes in quality control results should they occur when the reagent(s), calibration(s) or quality control material(s) exceed the expiration date.

NOTE: In general, all out-dated materials (which includes reagents, calibrators, standards, quality control materials and other consumables) must not be used for patient care unless authorized by the laboratory chief, or qualified designee.

(l) The Chief, Pathology and Laboratory Medicine Service, must have a written policy for extending the expiration date of reagents, calibrators, quality control and other consumable materials without compromising patient care.

1. If the materials are kept beyond the expiration date, it is recommended that the policy have a testing method to determine the acceptability of the

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materials without sacrificing the clinical usefulness of the test. It is recommended that the following NCCLS guidelines be consulted:

a. D12-A, guidelines on Immunoprecipitin Assays" (see subpar. 4.12r).

b. D13-T, "Agglutination Analyses: Characteristics of Antibody, Methodology, Limitations and Clinical Validation" (see subpar. 4.12s); and

c. LA1-A, "Assessing the Quality of Radioimmunoassay System" (see subpar. 4.12t).

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2. For blood gas (pO_2, pCO_2, HCO_3, pH) measurements, two-level quality control specimens (high and low), as a minimum, must be run every 8 hours. NOTE: NCCLS, C27-T, "Blood Gas Preanalytical Considerations: Specimen Collection, Calibration and Controls," is recommended as a quality control protocol (see subpar. 4.12g).

2.06 EXTERNAL PROFICIENCY TESTING PROGRAM

As an enhancement to the internal Quality Control Program, to ensure reliability of patient testing in the laboratory, and to maintain accreditation requirements, each Pathology and Laboratory Medicine Service and all ancillary testing sites, must subscribe to external surveillance programs as prescribed by the Director, Pathology and Laboratory Medicine Service, VA Central Office.

a. The VA National Center for Laboratory Accuracy and Standardization (VANCLAS) Program at VA Medical Center, Cleveland, OH, will serve as a technical resource center for all VA medical center laboratories and testing sites that require assistance for quality control, calibration and proficiency survey outlier problems.

b. All VA medical centers will maintain satisfactory performance in the VANCLAS Program, for each quantitative analyte developed for standardization by VANCLAS throughout the nationwide VA network (see Ch. 4).

c. External proficiency testing programs for surgical and cythopathology are described in Chapter 6.

2.07 TEST METHODS AND EQUIPMENT STANDARDS

a. Each Chief, Pathology and Laboratory Medicine Service must establish standards and policies for selection of tests, reflecting state-of-the-art methods and procedures. Each test method must have a clearly written manual available in each testing area to comply with NCCLS, GP2-A-2, "Clinical Laboratory Procedure Manuals," guidelines (see subpar. 4.12n). As a minimum the written test procedures must contain:

(1) The principle of the test;

(2) Specimen requirements;

(3) Reagents;

(4) Calibration frequency and procedure;

(5) Quality control;

(6) Test procedures;

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(7) Calculation section;

(8) Reference interval or test results;

(9) References; and

(10) Any pertinent information such as interferences (endogenous and exogenous) known about the test method.

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b. Procedure Manual

The procedure manual must be reviewed by qualified laboratory supervisory personnel on an annual basis, and the date of initial use and date of intended discontinuance must be noted in the beginning of the manual. The Chief, Pathology and Laboratory Medicine Service, or qualified designee, must date and sign the manual on an annual basis. The manual must be placed in the laboratory in an area that is readily accessible to persons performing tests.

c. Calibration and Standardization of Analytical Systems. Dependable analytical systems (methods, instruments, reagents, calibrators, primary and secondary standards with accurate assignment of values) must be used. The reagents, calibrators, standards, quality control materials must be stable and have a long shelf life.

(1) The laboratory must, as a minimum, follow the schedule recommended by the manufacturer for FDA-approved systems. More frequent calibration may be necessary with some analytes such as blood gases, especially with non-automated instruments.

(2) For in-house developed methods, or systems, the frequency of calibration will depend on the scientific data to ensure reliable testing provided by the laboratory.

(3) Verification of accuracy of testing of patient specimens shall be evaluated, whenever deemed necessary, on fresh, unfrozen materials with assignment values traceable to a definitive, reference, or consensus method. As an example, VANCLAS does have such materials available for cholesterol sodium, potassium, chloride, total protein, albumin, glucose, and Aspartate aminotransferase testing. As more materials become available and as more peer group consensus approved definitive and/or reference methods are present, VANCLAS will send them to each VA medical center to assess and assist in the standardization of accuracy of testing of other analytes to be designated, i.e., total birubin, blood gases, calcium, CK-MB isoenzyme, creatinine, glycated hemoglobin, HDL-cholesterol, magnesium, triglycerides, and uric acid. NOTE: For some analytes, this may cause failure of CAP Proficiency Testing results, if the CAP materials exhibit "matrix effect." VANCLAS will assist each VA medical center in resolving differences between VANCLAS and CAP results (see CH. 4). VANCLAS will work with VA Central Office's Pathology and Laboratory Medicine Quality Management Coordinator to ensure that CAP inspectors recognize that CAP Proficiency Testing materials may not behave like human specimens.

(4) The Chief, Pathology and Laboratory Medicine Service, shall establish a policy for calibration procedures and methods, which requires the laboratory to participate in and follow VANCLAS programs and guidelines.

d. Establishing and Verifying Method and Equipment Performance Specifications. Immediate suspension of patient testing will be imposed by

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the Chief, Pathology and Laboratory Medicine Service, whenever the critical analyte(s) (i.e., analytes whose inaccurate results endanger's the patient's life) exceeds the action limits as defined in chapter 4. There will be no testing of the analyte in question until the problem has been identified, corrected, and has met the VANCLAS requirements for satisfactory performance. All other regulated analytes that are not on the critical testing list will result in remedial and educational activities, but no discontinuance of patient testing. Each analytical component shall be of sufficient quality to ensure accurate and/or precise laboratory results, must be reported in a timely manner.

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(1) The Chief, Pathology and Laboratory Medicine Service, is responsible for having guidelines for selection of analytical systems commensurate with the equipment selection guidelines provided by the Director, Pathology and Laboratory Medicine Service, VA Central Office.

(a) For automated routine analytical instruments (including desk-top or alternate-site analyzers), consideration must be given to the selection of FDA-approved analytical systems.

(b) Selection should be based on documented evidence that the instrument:

1. Has good analytical precision (i.e., a long-term or between-run precision of automated chemistry analytical systems should generally have 5 percent coefficient of variation (C.V.) more or less, immunochemical systems 6 to 10 percent, and Radio Immunoassay (RIA) systems 11 to 20 percent);

2. Has been certified by the manufacturer;

3. That its analytical system is accurate with traceability to definitive, reference, and/or consensus method and certified reference materials, i.e., from the National Institute for Standards and Technology, Centers for Disease Control and Prevention, and CAP;

4. Does not require frequent calibration and preventive maintenance; and

5. Is dependable.

(c) Whenever possible, the major routine analytical systems must be interfaceable to the VA medical center DHCP computer system.

(d) If there are any doubts about the analytical accuracy, precision or dependability of an analytical system, especially if it is a new model or from a new vendor, the Director, Pathology and Laboratory Medicine Service, VA Central Office, must be informed immediately.

(e) Analytes measured from analytical test-kit procedures must be FDA-approved and meet the same general guidelines and standards of the analytical system. NOTE: Many kit methods may be manual tests and the precision requirements may exceed a 5 percent C.V., but should not exceed, as a maximum, 20 percent.

(f) Any in-house-developed methods, or modified analytical systems, must establish a written protocol to evaluate the precision, linearity, lower limits of detection, reference interval, and accuracy.

1. Standards must be written with clearly defined instrument preventive maintenance and function-check procedures.

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2. Criteria for reagent stability, calibration frequency, and appropriate quality control materials must be established. NCCLS guidelines for documenting the acceptability of a test method are:

a. EP10-T, "Preliminary Evaluation of Clinical Chemistry Methods," (see subpar. 4.12q).

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b. D12-A, "Immunoprecipitin Assays: Procedures for Evaluating the Performance of Materials," (see subpar. 4.12r).

c. D13-T, "Agglutination Analyses: Characteristics of Antibody, Methodology, Limitations, and Clinical Validation," (see subpar. 4.12s).

d. D14-T, "Enzyme and Fluorescence Immunoassays," (see subpar. 4.12t).

(g) The Chief, Pathology and Laboratory Medicine Service, shall be responsible for establishing a policy for validation of the manufacturer's claims on the performance characteristics of an analytical system.

1. All newly purchased analytical systems (including test kits and in-house developed systems) must follow NCCLS, EP 10-T, "Preliminary Evaluation of Clinical Chemistry Methods" (subpar. 4.12q), or similar protocol, to validate the manufacturer's claims on precision, linearity, accuracy or comparability of results and reference intervals. Potential sample or reagent carry-over problems, system drift or outliers results, reagent instability, and other analytic functions must be part of the evaluation process. For the validation of accuracy of results, fresh patient specimens should be used (see ch. 4). NOTE: VANCLAS should be consulted if there are any technical issues that need to be resolved.

2. The protocol of choice for validation of the method's analytical performance characteristics include the following NCCLS guidelines:

a. EP5-T, "User Evaluation of Precision Performance of Clinical Chemistry Devices," (see subpar. 4.12u).

b. EP-9-P, "User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples," (see subpar. 4.12v).

3. If the analytical system is replacing an existing system, parallel testing must be done to define comparability. NCCLS, C28-P guidelines on, "How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory," should be utilized (see subpar. 4.12o). NOTE: Reference interval validation or determination process is not the same as parallel testing,

4. Parallel testing must be used when lots of reagents, calibrators or quality control materials are to be changed. The written protocol must include the scope and design of the parallel testing, and the statistical model used, to ensure that the accuracy of testing of the patient specimens are not compromised.

5. All data must be kept according to the requirements in Appendix 2C.

e. Equipment and Supplies

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(1) Pathology and Laboratory Medicine Service shall purchase instruments, reagents, calibrators, quality control materials, and other required supplies and consumables in sufficient supply so that the quality of laboratory testing or patient care is not compromised. The reagents, calibrators, and quality control materials shall be of the highest quality, stable with long shelf life, and provide accurate patient values, which are traceable, whenever possible, to a definitive, reference, consensus or comparative method. NOTE: NCCLS GP6-P, "Inventory Control Systems for Laboratory Supplies," should be consulted (see subpar. 4.12l).

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(2) Every effort must be made to practice cost-containment without sacrifice of quality of the laboratory service. Whenever possible consideration should be given to regional group purchasing and/or other recommendations of the VA National Center for Cost Containment.

(a) Where feasible, the NCCLS, GP11-P guidelines on, "Cost Accounting in the Clinical Laboratory," should be implemented (see subpar. 4.12m).

(b) The acquisition of equipment, materials and other consumables must be accomplished according to the procedure and guidelines of VA's DHCP Software program, known as Integrated Funds Distribution Control Point Activity (IFCAP), which is operated by VA's Office of Acquisition and Materiel Management (OA&MM).

(3) The Chief, Pathology and Laboratory Medicine Service, is responsible for:

(a) Defining criteria for:

1. Acceptable storage conditions for reagents,

2. Standards,

3. Calibrators,

4. Quality control materials, and

5. Maintenance and function checks on equipment.

(b) Ensuring that equipment maintenance records are available in the testing area(s) and that these records are periodically reviewed by qualified supervisory personnel.

(c) A written policy on the appropriate labeling of reagents, chemicals, calibrators and quality control materials that meet CAP laboratory accreditation standards. It must include such items as:

1. Identity,

2. Titer strength or concentration,

3. Recommended storage requirements, and

4. Other pertinent information required for proper use, such as:

a. All materials must be dated the date of receipt, the date when opened or used, the date reagents were prepared, the contents of prepared reagents, and the expiration date.

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b. All toxic and biohazardous chemicals and radioactive materials must be labeled and stored according to the safety policies and procedures established in the laboratory's and facility's Safety Manual.

(4) Tolerance limits must be established for water purity, refrigeration, freezer, and room temperature.

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(5) Tolerances for allowable fluctuations and interruptions in electrical current must be known for instruments that are micro-processor driven and are sensitive to electrical current instabilities. NOTE: These should be provided by the manufacturer.

(6) The policy must include criteria on:

(a) Hazardous waste disposal,

(b) Safe work practices, and

(c) Internal and external disaster preparedness.

NOTE: NCCLS, GP5-T, "Clinical Laboratory Waste Management," (subpar. 4.12h) and NCCLS M29-T2, "Protection of Laboratory Workers from Infectious Diseases Transmitted by Blood, Body Fluids, and Tissue," guidelines (subpar. 4.12i) must be followed, as well as the facility's and laboratory's guidelines.

2.08 PATIENT TEST MANAGEMENT

a. Responsibilities of the Chief, Pathology and Laboratory Medicine Service. The Chief, Pathology and Laboratory Medicine Service, shall ensure that: NOTE: The following applies to all testing sites in each VA medical center that perform laboratory tests on patients for diagnosis, monitoring therapy or the progress of disease.

(1) Standards, procedures, and policies are developed for reporting of timely, accurate, reliable and clear test results. Policies for detection of potential errors or differences in test results for the same analyte between the clinical laboratory and all ancillary testing sites in the VA medical center will be established through the VA medical center's Ancillary Testing Committee. All laboratory test results must be carefully reviewed for accuracy of reporting by the testing personnel performing the test before the data is released to the physicians and wards. Supervisors of Laboratory Sections will review data as part of the total quality improvement process on a periodic basis as determined by the Pathology and Laboratory Medicine Service Quality Improvement Committee.

(2) Standards and policies are developed to:

1. Detect clerical errors in general;

2. Determine who is authorized to enter corrected results;

3. Develop methods of documentation and tracking errors and differences;

4. Develop follow-up procedures for correction of errors;

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5. Document and determine remedial measures, such as in-service continuing education; and

6. Determine who should be notified of errors in the event it affects, or alters, the outcome of the diagnosis, treatment, or any other medical decision regarding the care of the patient.

(3) A written policy on manual data review procedures is developed for all laboratory tests. All laboratory results (data) must be carefully reviewed and verified before they

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are available to physicians or the wards. Test results acceptable for release must be verified by the personnel performing the test. Data must be reviewed by the Section Supervisor to verify the accuracy of the manual data input and automated data transfer, and as part of ongoing quality improvement activities.. If an error is found on a released patient result, the appropriate designee will communicate immediately with the physician in charge of the patient. The Chief, Pathology and Laboratory Medicine Service, or designee, will ensure that the report is corrected in the DHCP computer system. Both original, and corrected results will automatically become part of the patient's permanent record.

(4) Clearly written policies and procedures are developed to:

(a) Review processes for electronic data transmission. For example, programs must be developed so that the DHCP computer system will check the entered data against predefined limits (established by the Chief, Pathology and Laboratory Medicine Service) for tests such that high, low and critical values are identified and flagged. Entries outside of the incompatible ranges will not be accepted.

1. Previous patient test results display a delta check.

2. All significant abnormalities must be identified by an audible "beep" and a visual "flag" observed next to the test values.

(b) Ensure correction of detected errors. For example, if the operator, or designee, is required to recheck the results and immediately call the patient's physician, nurse or ward personnel for all corrected values and indicate in the computer in the "comment" section the person they communicated the information to, the analyte in question, the time, and any other pertinent information for documentation.

(c) Ensure that test results are checked, regardless of the quality control results. Unlikely test results must be verified by other methods. If the Laboratory does not have a back-up instrument for certain methods, another VA medical center or community hospital laboratory should be used.

(d) Ensure that the review process is documented in the quality records of each testing site. This review summary must be included as a part of the Pathology and Laboratory Medicine Quality Assurance Improvement Report.

b. Patient Identification

(1) The testing site must have written policies which ensure the positive identification of the patient, and all patient specimens from the time the specimen is collected until testing has been completed and the results reported.

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(2) The testing site must have an appropriate specimen identification and accessioning system in use, and consistently applied, which assures that all specimens are uniquely identified in such a manner as to minimize sample mixups, mislabeling, etc.

c. Specimen Submission Labeling and Handling

(1) The testing site must have written policies and procedures for:

(a) Methods used for preparation of the patient,

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(b) The nature and amount of specimens to be collected,

(c) The need for special timing for specimen collection,

(d) The type and amounts of preservatives and anticoagulants, if applicable,

(e) The need for any special handling, and

(f) The need for appropriate clinical information about the patient.

(2) The policies and procedures described in this chapter must be included in the specimen collection manual. The specimen collection manual must be available to all specimen-collecting areas within the hospital and to areas outside the hospital which might be referring specimens for testing.

(3) In addition to assuring the positive identification of specimens, the testing site must assure optimum integrity of the specimens from the time of collection until testing has been completed, and the results reported. Storage, if possible, must be provided for blood/body fluid specimens that assures optimum integrity of specimens for a period determined to be appropriate, by the facility.

(4) The testing site must have written criteria for the rejection of unacceptable specimens, or the special handling of sub-optimal specimens, and must assure appropriate communication of that information to the requesting physician.

(5) The testing site must be able to track the date and time each specimen was received.

d. Test Requisition and Patient Information Requirements

(1) The testing site will perform tests only at the written, or electronic, request of an authorized person.

(2) Records of test requisitions, or test authorizations, must be retained for a sufficient period of time to meet the needs of the facility (app. 2C).

(3) The laboratory test requisition, or test authorization, must include:

(a) The patient's name,

(b) Social Security Number,

(c) The test to be performed,

(d) The date and time of the specimen collection,

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(e) Any other clinically relevant data as detailed in the Specimen Collection Manual, and

(f) The requesting physician, or the name of the individual responsible for utilizing the test results, who would also serve as the contact person to enable reporting of imminent life-threatening laboratory results, or critical values.

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e. Test Records

(1) Records of patient testing, including instrument printout if applicable, must be retained a minimum of 2 years if possible, in DHCP, based on the VA medical center's local capacity (app. 2C). NOTE: Records are to be disposed of in accordance with the Department's RCS (Records Control Schedule) 10-1, or other appropriate RCS.

(a) The name of the testing site location at which the test was performed will be printed on the test report.

(b) If the testing site is outside the medical center, the identity of the laboratory will be printed on the report.

(2) The tests results must be reported to the persons authorized by law to receive and use the medical information. Adequate systems must be in place to ensure that results are reported in a timely, accurate and reliable manner, ensuring patient confidentiality throughout the entire process.

(3) Procedures must be developed, and in use, for reporting imminent life-threatening laboratory results or critical values. This procedure must include notification of either the individual requesting the test, or the individual responsible for utilizing the test results. The notification must be documented in the patient's permanent record.

(4) The laboratory test report must include:

(a) The name of the patient;

(b) The Social Security Number;

(c) The name of the ordering physician;

(d) The date and time of the specimen, and the test name and units;

(e) The reference intervals, when possible.

(5) Reports generated by DHCP

(a) In the case of the interim reports generated by DHCP, intended to serve as the physician's work copy, the name of the requesting physician must be included.

(b) In the case of the cumulative report generated by DHCP, intended to serve as the permanent record copy, the name of the requesting physician may not be included, since there are multiple ordering physicians, and several sets of results appear on the same page.

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(6) The original report, or a duplicate of each report (including preliminary and final, and except for microbiology), must be retained in a manner that permits prompt retrieval of information by the testing site personnel and clinical personnel. NOTE: Current DHCP Programing deletes preliminary reports when final reports are issued. The DHCP Laboratory Expert Panel is currently resolving this problem.

(a) This report must be maintained as part of the patient's record.

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(b) The length of time that previously reported clinical laboratory data is retained on-line must be sufficient to meet the needs of the clinical staff, and should be at least 6 months to 1 year , depending on the VA medical center's local policy for data storage on DHCP. This allows data comparisons for both inpatient and outpatient use, in the event that a hard copy of the report is not immediately available (app. 2B). NOTE: If data is not available on-line, it must be accessible via the available archiving and/or de-archiving options.

(c) In accordance with 21 CFR 606, Subpart I, and AABB Standards, immunohematology records of patient testing, unit testing and donor testing must be retained for a minimum of 5 years (App. 2C) (see Ch. 5 for specific details regarding transfusion record retention).

(d) Surgical pathology reports must be retained for a minimum of 25 years (see Ch. 6 and App. 2C).

1. If this data is stored on the computer, certain specific details, including the accession number, the specimen type and the final diagnosis must be retrievable until the patient's death.

2. If data is not available on-line, it must be accessible via alternative data storage capabilities or in hard copy (see Ch. 6).

(7) For all specimens which are inadequate to perform testing, the test report must indicate information regarding the condition and disposition of the specimen.

(8) The laboratory must, upon request, make available information that affects the interpretation of test results, such as interfering substances, environmental conditions, etc.

f. Referral of Specimens. A VA testing site may refer specimens for testing only to a laboratory which possesses a valid license under the provisions of the Clinical Laboratory Improvement Act of 1988.

(1) A copy of the test results from the reference laboratory must be retained in the referring laboratory for 2 years (see App. 2C).

(2) The name and location of the laboratory which actually performs the laboratory testing must be included on the report before it is placed in the patient's record.

2.09 ADMINISTRATION OF THE LABORATORY'S QUALITY IMPROVEMENT PROGRAM

There must be an ongoing planned, systematic, and objective process for the monitoring and evaluation of the quality improvement plan, and the appropriateness of patient care provided by Pathology and Laboratory Medicine Service. Monitoring data will be compared to pre-established standards of

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acceptabilities (see Ch. 14). An action plan will be developed and evaluated when opportunities to improve patient care are identified. The Chief, Pathology and Laboratory Medicine Service, will establish a Quality Improvement Committee. NOTE: An example of a Quality Improvement Plan for Pathology and Laboratory Medicine Service can be found in Appendix 2A. A sample of the required Laboratory Quality Scorecard for each VA medical center, to be used by VA Central office and regional oversight groups, can be found in appendix 2B.

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a. Definitions and Amplifying Information for the Quality Improvement Committee:

(1) Aspects of Care

(a) Major service functions of aspects of care must be determined for both the clinical and administrative programs of Pathology and Laboratory Medicine Service.

(b) Multidisciplinary indicators must be developed for each major aspect of care, based on current JCAHO policy.

(c) Technical specialists and clinical service representatives, through effective interactions and group processes, determine and define the standards of care and indicators used for monitoring compliance with ratified standards.

(2) Criteria, along with VA medical center-developed thresholds, or expected levels of conformance to standards for evaluation, are developed for each indicator identified (see App. 2A and Ch. 14).

(3) Data collection is conducted on at least a quarterly basis (to be consistent with JCAHO guidelines) by designated personnel and forwarded to the section supervisor, or Chief, Anatomic Pathology Section, or Chief, Clinical Laboratory Section. Data is collected against indicators and the results reviewed for collected change and/or corrective action (see App. 2A and Ch. 14).

(4) An evaluation of the data is made and presented to the Pathology and Laboratory Medicine Quality Improvement Committee. The results and discussion are documented in the service's staff meeting minutes, noting action(s) taken, if any.

(5) When established thresholds are exceeded, areas which require improvement are identified and a plan for corrective action is implemented. If the data collection does not identify any areas of concern, or areas of improvement, after sufficient time elapses, a re-evaluation of the indicator is required to determine whether the indicator should be continued with a change in the threshold, or whether it should be discontinued.

(6) Pathology and Laboratory Medicine Service, after allowing sufficient times for change to occur, will evaluate the effectiveness of corrective actions(s) in order to determine if the action(s) resulted in a solution to the problem, and an improvement in patient care and services.

(7) There will be, at least, a quarterly review on the reporting of any trends, planned action, or results from each quality assurance indicator, by the facility Quality Manager. Issues and information obtained from data collection will be discussed at staff meetings for the benefit of clinical staff, and at the medical center's Quality Improvement Committee meetings.

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b. Responsibilities

(1) The Chief, Anatomic Pathology Section, Chief, Laboratory Medicine Section, staff pathologists, clinical scientists, and section supervisors, will develop the annual Quality Improvement Plan, and submit it to the Pathology and Laboratory Medicine Service Quality Improvement Committee for review.

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(2) The Chief, Pathology and Laboratory Medicine Service, is responsible for establishing and coordinating the Service's Quality Improvement Program and ensuring compliance.

(3) The Chief, Anatomic Pathology Section, Chief, Pathology and Laboratory Medicine Section, section supervisors, and clinical scientists are responsible for:

(a) Identifying appropriate clinical and administrative indicators;

(b) Developing and implementing a plan to monitor and evaluate indicators; and

(c) Taking action to correct identified problems.

c. Quality Improvement Committee

(1) Pathology and Laboratory Medicine Service Quality Improvement Committee is chaired by the Chief, Pathology and Laboratory Medicine, or designee, and consists of:

(a) The Chief, Anatomic Pathology Section and the Chief, Laboratory Medicine Section;

(b) Supervisory chemist;

(c) Supervisory microbiologist;

(d) Supervisor, anatomic pathology;

(e) Supervisor, blood bank; and

(f) Other pathologists, clinical scientists, and supervisors as appropriate to the size, complexity, and functionality of the laboratory.

(2) The Committee will meet on a monthly basis.

(3) The Pathology and Laboratory Medicine Service Quality Improvement Committee is responsible for:

(a) Reviewing and approving the Quality Improvement Plan,

(b) Making recommendations for improvement, and

(c) Overseeing the quality management activities for the service.

(d) Reviewing the Quality Improvement Plan annually.

2.10 REFERENCES

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k. Standards for Blood Banks and Transfusion Services, 15th edition, AABB; 1993.

l. Federal Register, Vol. 57, No. 40, February 28, 1882, Rules and Regulations, The Clinical Laboratory Improvement Amendments of 1988, Subpart P, Quality Assurance, Section 493: 1701; Patient Test Management, Section 493.1703; Quality Control, Section 493.1705; Proficiency Testing, Section 493.1707; Comparison of Test Results, Section 593.1711; Personnel Assessment, Section 493.1713; Communications, Section 1715; Complaint Investigations, Section 493.1719; Quality Assurance Records, Section 493.1721; Subpart Q, Inspection of Laboratories, Section 493.1777.

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AN EXAMPLE OF A QUALITY IMPROVEMENT PLAN FOR PATHOLOGY AND LABORATORY MEDICINE SERVICE

1. OVERVIEW

Quality improvement in Laboratory Medicine and Pathology is based on systematic surveillance that determines whether the laboratory's contribution to patient care is of high quality. Three discrete functional areas exist within the laboratory:

a. The clinical laboratory,

b. Anatomic pathology, and

c. The blood bank.

2. IMPORTANT ASPECTS OF SERVICE

Important aspects of service are those that are:

a. High volume tests (occur frequently or affect a large number of patients);

b. High risk tests (place patients at risk of serious complications or deprive patients of substantial benefit if not performed/administered correctly, in a timely manner and/or with proper indication);

c. Low risk tests (place patients at risk of moderate to mild complications, discomfort, inconvenience, or emotional distress, if not performed properly, or a result is lost, attributed to another patient, or not delivered in a timely manner); and/or

d. Problem prone (tend to cause problems for staff or patients); for example, the technical areas of: NOTE: Smaller Department of Veterans Affairs (VA) medical centers may not have all of these functional areas.

(1) Phlebotomy,

(2) Biochemical testing,

(3) Emergency testing,

(4) Coagulation testing monitoring anticoagulant therapy,

(5) Therapeutic drug monitoring,

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(6) Antibiotic susceptibility,

(7) Cultures (blood, sputum, throat, urine, etc.),

(8) Blood and blood component therapy,

(9) Needle biopsies and frozen sections, and

(10) Pathology diagnoses.

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e. Correlation of post-mortem findings with premortem diagnosis.

3. SUGGESTED MONITORS AND/OR INDICATORS (See App. 14D.) NOTE: Each VA medical center Pathology and Laboratory Medicine Service may design its own criteria and thresholds. This list is only an example.

a. Clinical Laboratory

(1) Appropriateness of laboratory test requests

(a) Criteria: Duplicate test requests exceeding the locally established guidelines for ordering that test
Threshold: > 5 percent duplicates

(b) Criteria: Inappropriate test requests (e.g., lithium requests on pts. not on lithium medication)
Threshold: > 0 percent inappropriate

(2) Appropriateness of Specimens Submitted

Criteria: Inappropriate specimens submitted for selected tests, i.e. wrong container, wrong tube type, incorrect preservative, patient ID conflict, etc.
Threshold: > 5 percent inappropriate

(3) Accuracy of Laboratory Testing

Criteria: Acceptable performance in the proficiency testing survey program of the College of American Pathologists (CAP) and satisfactory performance in the VA National Center for Laboratory Accuracy and Standardization (VANCLAS) Program
Threshold: > 2 repeated outliers for the same constituent within a 2-year period; for CAP: two consecutive surveys with outliers for the VANCLAS Program, i.e., overall percent bias exceeding VANCLAS standards for the same constituent

(4) Appropriateness of TAT (Turn Around Time(s)) for Laboratory Testing

Criteria: Urgent (life-threatening) 1 results reported within 1 hour
Threshold: > 5 percent not reported within established TAT, or
> 0 incident reports associated with delays attributable to Pathology and Laboratory Medicine Service

(5) Effectiveness of Inpatient Phlebotomy Performed by the Laboratory

Criteria: Rate of successful venipunctures on morning draws

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Threshold: > 5 percent "unable to draw" per ward on a monthly basis

(6) Communication of Critical Values

Criteria: Appropriate communication and documentation of provider notification of critical values

Threshold: < 100 percent of critical values notification properly entered

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(7) Appropriate Reporting of Laboratory Test Results

Criteria:	Appropriate entry of corrected test results
Threshold:	> 5 instances a month, or a percentage involving deletion of "incorrectly reported as" comments from previously verified, released results

b. Anatomic Pathology

(1) Accuracy of Surgical Pathology Reports

(a) Criteria:	Correlation of diagnoses made on frozen sections compared to diagnoses on permanent sections
Threshold:	> 98 percent correlation
(b) Criteria:	Correlation of diagnoses reported with that of diagnosis obtained from review by a second pathologist including cases identified for re-review by Surgical Case Review or other clinical conferences
Threshold:	> 2 percent major discrepancies (CAP Category C) in which a diagnosis was changed > 5 percent minor discrepancies (CAP Categories A or B) in which no change in diagnosis or therapy was required; however, a modified report was required

(2) Accuracy of Autopsy Reports

Criteria:	Correlation of diagnoses reported with that of review by a second pathologist
Threshold:	> 2 percent major discrepancies in which a diagnosis was changed > 5 percent minor discrepancies in which no change in diagnosis or therapy was required; however, a modified report was required

(3) TAT for Pathological Reports

Criteria:	Appropriateness of turnaround times for pathology reports: Surgical pathology 2 days Autopsy 30 days Cytology 2 days
Threshold:	> 75 percent reported within established TAT

(4) Documentation of Required Physician Notification

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(a) Criteria: Documentation of physician notification if a diagnosis of malignancy is made on tissue and review of the patient's diagnoses on file reveals that no prior malignancy existed.

Threshold: < 100 percent of cases properly documented

(b) Criteria: Documentation of physician notification if the second review reveals a major discrepancy, i.e., change in diagnosis or therapy is necessary

Threshold: < 100 percent of cases properly documented

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(5) Appropriateness of Premortem Diagnosis (Ref: OMB (Office of Management and Budget) Circular A-123, and Pathology and Medical Laboratory Service, JCAHO (Joint Commission on Accreditation of Healthcare Organizations), 1989.)

Criteria:	Correlation of premortem and postmortem diagnoses
Threshold:	> 10 percent of autopsies yield major discrepant diagnoses between premortem and postmortem diagnoses

c. Blood Bank

(1) Appropriateness of red blood cell requests

(a) Criteria:	Prospective and retrospective evaluation of transfusion indications, of each non-preoperative request and perioperative request, respectively
Threshold:	> 1 percent of patients transfused for which the indication for transfusion was inappropriate after peer review based on guidelines established by the facility
(b) Criteria:	Retrospective evaluation of transfusion indications for all single unit transfusions
Threshold:	> 1 percent of patients transfused for which the indication for transfusion was inappropriate after peer review based on guidelines established by the facility
(c) Criteria:	Adherence to the Maximum Surgical Blood Order Schedule (MSBOS) for preoperative requests
Threshold:	> 5 percent of preoperative requests exceeding the MSBOS, or > 65 percent of blood crossmatched not utilized during the perioperative period NOTE: These percentages may vary by facility.
(d) Criteria:	Crossmatch: Transfusion Ratio (C:T)
Threshold:	> 2.5 percent overall, this should be specified for each major clinical service, e.g., 1.75 percent for Medical Service or 3 percent for Surgical Service

(2) Appropriateness of Fresh Frozen Plasma Requests

Criteria:	Prospective and retrospective evaluation of transfusion indications of each request
Threshold:	> 1 percent of patients transfused for which the indication for transfusion was inappropriate after peer review based on guidelines established by the facility

(3) Appropriateness of Platelet Requests

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Criteria:	Prospective and retrospective evaluation of transfusion indications of each request
Threshold:	> 1 percent of patients transfused for which the indication for transfusion was inappropriate after peer review based on guidelines established by the facility

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(4) Appropriateness of Cryoprecipitate Requests

Criteria:	Prospective and retrospective evaluation of transfusion indications of each request
Threshold:	> 1 percent of patients transfused for which the indication for transfusion was inappropriate after peer review based on guidelines established by the facility

(5) Transfusion Reaction Rate

Criteria:	Number and type of transfusion reactions
Threshold:	Overall rate of > 1 percent OR 0 percent acute hemolytic reactions

(6) Incidence of Transfusion Transmitted Diseases

Criteria:	Number and type of incidents of transfusion-transmitted diseases, including, but not limited to, hepatitis, HIV, HTLV-1 (both clinical disease and seroconversions)
Threshold:	> 10 percent of patients developing post-transfusion hepatitis 0 percent of patients developing HIV infection or seroconversion of those transfused since HIV antibody testing was implemented (1985) 0 percent of patients developing HTLV-1 infection or seroconversion of those transfused since HTLV-1 antibody testing was implemented in 1989

(7) Appropriateness of the Autologous Transfusion Program

(a) Criteria	Autologous transfusion rate, i.e., autologous versus total perioperative transfusions
Threshold	Assessment phase - yet to be determined
(b) Criteria	Underutilization rate, i.e., patients also requiring allogenic (homologous) transfusion
Threshold	> 10 percent of patients also require allogenic (homologous) units of red blood cells (RBC)

(8) Incidence of Blood Product Labelling Errors

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(a) Criteria	Incidence of blood labelling errors, i.e., errors which may potentially result in inappropriate transfusion of blood to a patient and might adversely effect the patient
Threshold	0 instances of labelling errors

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(9) Appropriateness of Turnaround Time for Emergency Requests

(a)	Criteria	Incidence of occurrence screen reports or patient incident reports associated with delays in providing blood or blood components
	Threshold	0 occurrence screen and/or patient incident reports associated with delays attributable to Pathology and Laboratory Medicine personnel

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A SAMPLE OF THE LABORATORY QUALITY SCORECARD

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A SAMPLE OF THE LABORATORY QUALITY SCORECARD--Continued

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A SAMPLE OF THE LABORATORY QUALITY SCORECARD--Continued

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A SAMPLE OF THE LABORATORY QUALITY SCORECARD--Continued

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A SAMPLE OF THE LABORATORY QUALITY SCORECARD--Continued

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COMPARISON OF RECORDS RETENTION REQUIREMENTS - CLIA/CAP/VA

NOTE: Records may be stored as hard copy or as Decentralized Hospital Computer Program (DHCP) and/or electronic format, to meet individual Department of Veterans Affairs (VA) medical center needs.

ITEM	CLIA '88*	CAP	VA	COMMENTS
1. CLINICAL PATHOLOGY				
a. Specimens:				
(1) Serum/CSF/Body fluids	-	24 hrs.	24 hrs.	
(2) Specimens from blood bank donors and recipients	-	7days post-transfusion (or 10 days post- cross match)	Same as CAP	
(3) Peripheral blood smears/body fluid smears	-	7 days	1 mo.	
(4) Bone Marrow smears	20 years	-	20 years	
(5) Permanently stained slides microbiology (gram, trichrome, etc.)	-	7 days	1 mo.	
b. Clinical Pathology Reports:				
(1) Patient test	2 yrs.	2 yrs.	2 yrs.	From report date reports (preliminary and final), including reference laboratory reports
(2) Other than patient reports (original and copies of clinic record-laboratory reports used for examination of individuals	-	-	6 mos.	

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other than patients.

* The test requisition and/or the test report maintained as part of the patient's chart or medical record complies with CLIA'88 requirement if the requisition is available to the laboratory at the time of testing and available to inspection groups upon request.

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ITEM	CLIA '88	CAP	VA	COMMENTS
CLINICAL PATHOLOGY (Continued)				
(3) Bone Marrow reports	-	20 yrs.	20 yrs.	
c. Clinical Pathology Records:				
(1) Test requisitions not on DHCP	2 yrs.	-	2 yrs.	
(2) Accessions records	-	2 yrs.	2 yrs.	
(3) Quality control records	2 yrs.	2 yrs.	2 yrs.	From date of initial test (CLIA)
(4) Proficiency testing records and Records of remedial action for PT failure	2 yrs.	-	2 yrs.*	From date of participation in PT event
(5) Copy of each test procedure	2 yrs.	-	2 yrs.*	From date of initial use of procedure to the date procedure is discontinued plus 2 years
(6) Laboratory methods file				Dispose after becoming obsolete or when replaced by a new card.
(7) Instrument maintenance records	-	Life of instrument	Life of instrument	
(8) Personnel records	-	30 yrs.	30 yrs.	
2. BLOOD BANK**				
a. All donor and	-	5 yrs.	Indefinite	Per American recipient records

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				Association of Blood Banks (AABB) standards
b. Records of employee signatures, initials and identification codes	-	5 yrs.	Indefinite	Per AABB standards

*Except in the Blood Bank where it must be 5 years based on AABB standards
**These guidelines equal or exceed AABB requirements

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ITEM	CLIA '88*	CAP	VA	COMMENTS
BLOOD BANK (Continued)				
c. QC (Quality control) records	-	2 yrs.	5 yrs.	Per AABB standards
d. Immunohematology QC activity records	5yrs.	5 yrs.	5 yrs.	
e. Records of permanently deferred donors	-	Forever	Forever	Including donor notification
f. Immunohematology Test Records	5 yrs.	5 yrs.	5 yrs.	
g. Immunohematology test report (Preliminary & Final)	2 yrs.	2 yrs.	5 yrs.	From report date
h. Blood and blood products quality control records	5 yrs.	5 yrs.	5 yrs.	After processing records have been completed or 6 mo. after the latest expiration date, whichever is later.
i. Blood bank monitoring file	-	-	5 yrs.	
j. Blood donor file	-	-	Indefinite	
k. Blood issue file	-	-	5 yrs.	After date of last entry
l. Blood source file	-	-	Indefinite	
m. Blood transfusion medical file	-	5 yrs.	-	After information has been recorded in

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	the patient's medical record
n. Therapeutic procedures (Phlebatomy hemapherisis or outpatient transfusion	5 yrs.
o. Notification to recipients of potential exposure to transfusion transmitted diseases	5 yrs.

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ITEM	CLIA '88*	CAP	VA	COMMENTS
3. ANATOMIC PATHOLOGY				
a. Surgical Pathology:				
(1) Tissue examination record (copies of tissue examinations - maintained in numerical order)	-	-	25 yrs.	Need not be hard copies; alternative is acceptable
(2) Wet Tissue	-	2 weeks	2 weeks	As long as it serves a useful purpose after final report
(3) Paraffin blocks (including oral pathology-CLIA)	2 yrs.+	5 yrs.	10 yrs.***	
(4) Slides (including oral pathology-CLIA)	10 yrs.+ 10 yrs.+	20 yrs.+ 20 yrs.+	25 yrs.*** 25 yrs.***	
(5) Accession log records		-	1 yr.	5 yrs.
(6) Maintenance records		-	2 yrs.	2 yrs.
b. Cytology:				
(1) Slides (negative - unsatisfactory)	5 yrs.+	5 yrs.+	5 yrs.+	
(2) Slides (suspicious - positive)	5 yrs.+	20 yrs.+	25 yrs.+***	
(3) Reports	-	20 yrs.	25 yrs.***	
(4) Accession log records		-	1 yr.	5 yrs.***
(5) Maintenance records		-	2 yrs	2 yrs
c. Autopsy Pathology:				

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(1) Wet Tissue	-	6 mos.	6 mos.	After final report is issued, and as long as it serves a useful purpose.

*** VA retention periods will be followed rather than those of the CAP.
+ From date of exam.

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ITEM	CLIA '88*	CAP	VA	COMMENTS
3. ANATOMIC PATHOLOGY (Continued)				
(2) Paraffin blocks	-	5 yrs.	10 yrs.	After final report
(3) Slides	-	20 yrs.	25 yrs.	Indefinitely***
(4) Reports	-	20 yrs	50 yrs.	After final report
(5) Accession log records	-	1 yr.	5 yrs.	After final report
(6) Maintenance	-	2 yrs.	2 yrs.	
(7) Autopsy protocol file	-	-	25 yrs.	
(8) Morgue record file (daily record of morgue refrigerator temperatures and copies of reports of inspection of the morgue).	-	-	2 yr.	

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*** VA retention periods will be followed rather than those of the CAP.

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COMPARISON OF CITATIONS FOR REGULATORY AND ACCREDITATION STANDARDS FOR VA MED TESTING SITES THAT PERFORM LABORATORY TESTS FOR PATIENT CARE

VA STANDARD	CAP	JCAHO	DHHS (HCFA)	DL (OSHA)	\ M-2,
1. PROCEDURES MANUAL (Written policies and procedures)					Chapt
a. Procedure approved, signed, dated by the Director			493.1211bc		Chapt
b. Change in procedure approved, signed, dated by the current Director			493.1211bc		Chapt
c. Current for tests performed	30.0130	PA.6.4.1.3			Chapt
d. Reviewed annually by qualified supervisory lab personnel	30.0140		493.1211bc	1050(f)	Chapt
e. Maintain date of initial use and discontinuance (2 yrs.)			493.1211bc		Chapt
f. Present in testing area	30.012	PA.6.4.1.3			Chapt
g. Procedures include					
(1) Preparation of patients			43.1103bc		Chapt
(2) Specimen collection	30.0150	PA.6.4.2.3.1	493.12111bc	1050(f)	Chapt
(3) Specimen labeling			493.11032bc		Chapt
(4) Specimen preservation	30.0150	PA.6.4.1.3.2	493.12111bc	1050(f)	
(5) Conditions of specimen transport			493.11032bc		
(6) Criteria for specimen rejection			493.1211bc		
(7) Specimen storage criteria			493.1211bc		

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VA STANDARD	CAP	JCAHO	DHHS (HCFA)	DL (OSHA)	V M-2,
(8) Test performance (step by step)	30.0150	PA6.3.1.3.6	493.1211bc		
(9) Instrument calibration	30.0150	PA6.4.1.3.3	493.1211bc		Chapt
(10) Reportable range for patient test results			493.1211bc		Chapt
(11) Quality Control	30.0150	PA6.4.1.3.4	493.1211bc	1050.(f)	Chapt
(12) Remedial action requirements	30.0150	PA6.4.1.3.4	493.1211bc	1050(f)	Chapt
(13) Limitations in methodologies			493.1211bc		
(14) "Normal" reference intervals			493.1211bc		
(15) Procedure(s) for life-threatening laboratory results or critical values			493.1211bc	1050.(f)	
(16) References (literature)			493.1211bc	1050(f)	
(17) System for reporting patient results			493.1211bc		
(18) Course of action in event test system inoperable			493.1211bc		
(19) Equipment performance evaluation		PA6.4.1.3.5			
2. REAGENTS					Chapt
a. Records of date of reagent preparation and expiration dates	30.0160		493.1205bc	1050.(e)	Chapt
b. Records checked on a scheduled basis by qualified supervisory laboratory personnel	30.0170			1050.(e)	Chapt
c. Reagents stored according to manufacturer's requirements	30.0180		493.1205bc	1050(e)	Chapt
d. Reagents used within time period indicated by manufacturer	30.0190		493.1205bc	1050(e)	Chapt
3. EQUIPMENT/INSTRUMENT MAINTENANCE/CALIBRATION	30.0200				Chapt
a. Directions available in testing area for proper maintenance of any equipment or instrument used in testing	30.0200				Chapt

VA STANDARD	CAP	JCAHO	DHHS (HCFA)	DL (OSHA)	V M-2,
b. Perform maintenance and function checks as defined by manufacturer			493.1215bc		Chapt
c. Document maintenance and function checks			493.1215bc		Chapt
d. Maintenance records available in testing area/periodically reviewed by qualified supervisory laboratory personnel	30.0210			1050.(f)	Chapt
e. Follow calibration and calibration verification procedure using calibrator materials specified by manufacturer (FDA approved instruments)			493.1217bc		Chapt
f. Perform calibration verification every 6 months and whenever testing conditions are altered			493.1217bc		Chapt
4. PERSONNEL					Chapt
a. Physician responsible for immediate ongoing testing performed in the specific testing area	30.0220	PA.1.1.1 PA.6.4.1.1		1283.	Chapt
b. Have personnel who meet qualifications and responsibilities as specified for:			493.1403b		
(1) Laboratory Chief			493.1441c 493.1409b		Chapt
(2) Technical Consultant			493.1415b		Chapt
(3) Clinical Supervisor			493.1453c 493.1447c		Chapt

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VA STANDARD	CAP	JCAHO	DHHS (HCFA)	DL (OSHA)	V M-2,
(4) Technical Supervisor (5) General Supervisor			493.1459c		Chapt
c. Person(s) performing the test have adequate, specific training and orientation to perform the tests offered; qualified personnel	30.0230	PA.6.4.1.2	493.1421b 493.1487c	1050.(c)	Chapt
d. Current list of personnel who are authorized to perform ancillary testing	30.0240	PA.6.4.1.1		1050.(c)	Chapt
e. Tests, that the personnel who are authorized to perform, specified	30.0250			1050.(c)	Chapt
5. QC (QUALITY CONTROL)					Chapt
a. Verification of method performance specifications			493.1213bc		Chapt
b. Documented QC checks on all tests each day of use (with positive and reference samples)	30.0260	PA.6.4.1.4	493.1202bc		Chapt
c. QC records maintained	30.0270	PA.6.4.1.5	493.1202bc	1050(f)	Chapt
d. Identified problems resolved		PA.6.4.1.4	493.1202bc		Chapt
e. Two levels of QC (minimum) each day of testing or each shift					Chapt

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VA STANDARD	CAP	JCAHO	DHHS (HCFA)	DL (OSHA)	V M-2,
6. TEST REQUESTS/SPECIMEN RECEIPT AND HANDLING					
a. Written or electronic request by an authorized person			493.1105bc		Chapt
b. Specimens uniquely identified			493.1103bc		Chapt
7. REPORTS/RESULTS					
a. Critical review and verification of results by licensed physician or surgeon or a person licensed (qualified person)				1050.(h)	Chapt
b. System for reporting results adequate:					Chapt
(1) Results timely, accurate, reliable			493.1109bc		Chapt
(2) Results clear and retained on chart or other acceptable location	30.0300		493.1109bc		Chapt
(3) Results confidential/released to only authorized persons only			493.1109bc		Chapt
(4) "Reference" intervals available to authorized persons			493.1109bc		Chapt
(5) Name and address of laboratory location at which the test was performed			493.1109bc		Chapt
c. Reports maintained (minimal time defined)			493.1109bc		Chapt

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VA STANDARD	CAP	JCAHO	DHHS (HCFA)	DL (OSHA)	V M-2,
8. RECORDS					
a. Unique identification of the specimen (patient)		"Audit trail" PA.6.4.1.5	493.1107bc		Chapt
b. Date/time of specimen receipt in laboratory			493.1107bc	1050.(f)	Chapt
c. Condition and disposition of specimens that do not meet the laboratories' criteria			493.1107bc		Chapt
d. Indicate (by initial, signature) who performed each of the tests	30.0280		493.1107bc		Chapt
e. Records maintained (minimal time)			493.1107bc	1050.(f)	Chapt
9. PROFICIENCY TESTING					Chapt
a. Evidence of participation in a proficiency testing program appropriate to size and scope of testing performed	30.0320		493.801bc	1050.(b)	Chapt M2.233
b. Test proficiency samples in same manner as patient samples			493.801bc		Chapt
c. Active review of proficiency testing results	30.0330				Chapt
d. Corrective action in response to unacceptable results	30.0330		493.803bc		Chapt M2.233
e. Successful participation (as defined) in approved proficiency testing program			493.803bc	1050.(b)	Chapt

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VA STANDARD	CAP	JCAHO	DHHS (HCFA)	DL (OSHA)	V M-2,
10. SAFETY					Chapt
a. Safety policies and procedures written and adequate for ancillary testing site's scope of activities	30.0340		493.1204bc	1910.103	Chapt
b. Written procedures detailing procurement, handling, and disposal of all specimens in a manner that minimizes hazards to personnel	30.0350			1910.103	Chapt
c. Facilities ensure adequate space and ventilation			493.1204bc 493.1204bc	1050.(d)	Chapt
d. Safety precautions posted/ observed for physical and biohazards materials					Chapt
e. Safety equipment (e.g., hoods) properly installed and regulated				1050.(d)	Chapt
f. Instruction in case of fire or emergency posted				1050.(d)	Chapt
11. QI (QUALITY IMPROVEMENT)					Chapt
Establish and follow written policies and procedures for a comprehensive QI program to monitor and evaluate the ongoing and overall quality of the total testing process		QA.1 QA.4	493.1701		Chapt

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